K013424

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Summary of Safety and Effectiveness for the Intramedullary Fixation System for the Hand

Submitted by

DEC 2 0 2001

Hand Innovations, Inc.
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Contact Person: Al Weisenborn
Device Trade Name: Intramedullary Fixation System for the Hand
Common Name: K-Wire
Classification Name: Smooth or threaded metallic bone fixation fastener, per 21 CFR § 888.3040

Identification of a Legally Marketed Predicate Device

The Intramedullary Fixation System for the Hand is substantially equivalent to the Intramedullary Fixation System for the Hand that is legally manufactured by Medcanica and marketed pursuant to premarket notification K991064.

Device Description

The Intramedullary Fixation System for the Hand is a sterile, single use, disposable device that is delivered non-toxic. The Intramedullary Fixation System for the Hand consists of the Slotted Awl Assembly, the Implantable Nail Handle Assembly, and Exchange Guide and Bend Tube.

Prior to use the implantable nail assembly is nested in the slotted awl assembly. The slotted awl assembly has a trocar point. The implantable nail has a blunt point that is positioned just behind the trocar point of the slotted awl. The sharp point of the slotted awl assembly is passed through a small incision. A hole is drilled into the metacarpal bone by twisting the assembled handles back and forth. After gaining access to the intramedullary space, the slotted awl handle is held stationary while the implantable nail is then advanced distally from the base of the metacarpal bone.

The awl handle is then withdrawn and removed for advancement of the implantable nail. The implantable nail is then cut adjacent to the nail handle. Using the bending tube end of the exchange guide and bend tube the implantable nail is bent to 90° with the apex of the

bend at the implantable nail insertion site. The nail is trimmed so that the end is below the skin. The small piece remaining will facilitate removal of the implantable nail subsequent to healing. The implantable nail will remain implanted for approximately six weeks. Upon healing of the fracture, the implantable nail is percutaneously removed.

In the event that it is desired to reform the implantable nail or implant a smaller nail, this may be accomplished without loosing access to the medullary canal. The exchange guide is advanced along the implantable nail into the medullar space. Once the medullar space is accessed, the nail is removed. Another nail may be placed into the medulla by inserting it into the groove of the exchange guide. After the nail has been inserted into the medullar space, remove the exchange guide.

An optional locking device may be used to minimize rotation of the implantable nail. The device consists of a pointed stainless steel cannula mounted to a polymeric handle. After the implantable nail is bent to a 90-degree angle, the locking sleeve is positioned over the end of the implantable nail and manually advanced downward through the cortical perforation and into the metaphysis. The locking device is then advanced until tactile feedback confirms ratchet engagement. The locking device may be further advance to the desired depth. When resistance is felt, the locking nail is impacted into its final position with a few sharp taps. The nail and locking sleeve are simultaneously trimmed.

Intended Use

The Intramedullary Fixation System is indicated for the fixation of extra-articular fractures of the long bones of the hand including the metacarpals and the proximal and middle phalanges. The optional locking device may be used to minimize axial and rotational motion of the implantable nail during healing.

Summary of Technological Characteristics

Twelve (12) technological characteristics of the Intramedullary Fixation System for the Hand were compared to the K-wire manufactured by MicroAire Surgical Equipment and found to be equivalent.

Summary of Performance Data

The Intramedullary Fixation System for the Hand meets the requirements of the following recognized consensus standards.

- ASTM F138 – 97, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
- ASTM F899 – 95, Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments
- ASTM F86 – 91, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants

- ASTM F366 – 82 (Reapproved 1993), Standard Specification for Fixation Pins and Wires

Additionally, nine (9) bench tests were performed to establish the safety and efficacy of the device.

Bench testing of both devices also demonstrated equivalence. Testing included stiffness/yield, cutting geometry comparison, and drilling test.

The tissue/bone contact materials of the device have been carefully selected for their long history of biocompatibility. The materials meet the requirements of the previously referenced recognized consensus standards.

Since the Intramedullary Fixation System for the Hand meets the requirements of the stated standards and embodies technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The Intramedullary Fixation System for the Hand was designed utilizing design controls compliant with the Quality System Regulation. The Intramedullary Fixation System for the Hand will be manufactured per specifications and good practices that ensure the device is safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Al Weisenborn
Hand Innovations, Inc.
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Miami, Florida 33176-2227

Re: K013424
Trade/Device Name: Intramedullary Fixation System for the Hand
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: October 9, 2001
Received: October 16, 2001

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D
Director
Division of General, Restorative, and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K013424

Device Name: Intramedullary Fixation System for the Hand

Indications for Use:

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013424

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)